EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

1. Related Application.

This application is a continuation-in-part of Applicant's co-pending application Serial No. 06/796,009 filed November 7, 1985 entitled Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft.

2. Field of the Invention.

The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

3. Description of the Prior Art.

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from an expandable heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of each structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermine the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the

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layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catheterization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical

characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angioplasties of graft-artery anastomotic strictures and postendarterectomy recurrent stenoses. Percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; and allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft. Therefore, the art has sought an expandable intraluminal vascular graft, and method and apparatus for expanding the lumen

of a body passageway which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway; and can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft.

SUMMARY OF THE INVENTION

In accordance with the invention the foregoing advantages have been achieved through the present expandable intraluminal vascular graft. The present invention includes a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the walls surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; the tubular shaped member having a first diameter which permits intraluminal delivery of the thin-walled tubular member into a body passageway having a lumen; and the tubular member having a second, expanded diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular shaped member may be expanded and deformed to expand the lumen of the body passageway.

A further feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly

spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots. Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member. An additional feature of the present invention is that the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter. A further feature of the present invention is that the tubular shaped member may have a biological inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for implanting a prosthesis within a body passageway. The method of the present invention comprises the steps of: utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; disposing the prosthesis upon a catheter; inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the porsthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

A further feature of the present invention is that the portion of the catheter in contact with the prosthesis may be collapsed, and the catheter removed from the body passageway. A further feature of the present invention is that a catheter having an expandable, inflatable portion associated therewith may be utilized; and expansion of the prosthesis and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

A further feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots. Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for intraluminally reinforcing a body passageway. The present invention includes: an expandable and deformable, thin-walled tubular prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis; and a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining

the expandable and deformable tubular prosthesis on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway. A further feature of the present invention is that the mounting and retaining means may comprise a retainer ring member disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable and deformable tubular prosthesis.

The expandable intraluminal vascular graft, method for implanting a prosthesis within a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; and permits expansion of the graft to a variable size dependent upon conditions within the body passageway.

BRIEF DESCRIPTION OF THE DRAWINGS:

In the drawings:

FIG. 1A is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. 1B is a perspective view of the graft, or prosthesis, of FIG. 1A, in its expanded configuration when disposed within a body passageway;

FIG. 2 is a cross-sectional view of the prosthesis taken along line 2-2 of FIG. 1B;

FIG. 3 is a cross-sectional view of an apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, illustrating a prosthesis, or intraluminal vascular graft, in the configuration shown in FIG. 1A;

FIG. 4 is a cross-sectional view of the apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, with the graft, or prosthesis, in the configurations shown in FIG. 1B; and

FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION:

In FIGS. 1A and 1B, an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway, 70 is illustrated. It should be understood that the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention, insofar as the methods, apparatus, and structures of the present invention may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways. For example, expandable prostheses 70 may also be used for such purposes as: (1) supportive graft placement within blocked arteries opened by transluminal recanalization, but which are likely to collapse in the absence of an internal support; (2) similar use following catheter passage through mediastinal and other veins occluded by inoperable cancers; (3) reinforcement of cathether created intrahepatic communications between portal and hepatic veins in patients suffering from portal hypertension; (4) supportive graft placement of narrowing of the esophagus, the intestine, the ureters, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" emcompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" emcompasses any duct within the human

body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIGS. 1A and 1B, the expandable intraluminal vascular graft, or prosthesis, 70 is shown to generally comprise a tubular member 71 having first and second ends 72, 73 and a wall surface 74 disposed between the first and second ends 72, 73. Tubular member 71 has a first diameter, d, which, to be hereinafter described in greater detail, permits intraluminal delivery of the tubular member 71 into a body passageway 80 having a lumen 81 (FIG. 3). With reference to FIG. 1B, upon the application from the interior of the tubular member 71 of a radially, outwardly extending force, to be hereinafter described in greater detail tubular member 71 has a second, expanded diameter, d', which second diameter d' is variable in size and dependent upon the amount of force applied to deform the tubular member 71.

Tubular member 71, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, 70 may come into contact. Tubular member 71 must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular membr 71 to be expanded and deformed from the configuration shown in FIG. 1A to the configuration shown illustrated in FIG. 1B and further to permit the tubular member 71 to retain its expanded and deformed configuration with the enlarged diameter d' shown in FIG. 1B and resist radial collapse. Suitable materials for the fabrication of tubular member 71 would include silver, tantalum, stainless steel, gold,

titanium or any suitable plastic material having the requisite characteristics previously described.

Preferably, tubular member 71 is initially a thin-walled stainless steel tube having a uniform wall thickness, and a plurality of slots 82 are formed in the wall surface 74 of tubular member 71. As seen in FIG. 1A when tubular member 71 has the first diameter d, the slots 82 are disposed substantially parallel to the longitudinal axis of the tubular member 71. As seen in FIG. 1A, the slots 82 are preferably uniformly and circumferentially spaced from adjacent slots 82, as by connecting members 77, which connecting members 77 preferably have a length equal to the width of slots 82, as seen in FIG. 1A. Slots 82 are further uniformly spaced from adjacent slots 82 along the longitudinal axis of the tubular member 71, which spacing is preferably equal to the width of connecting members 77. Thus, the formation of slots 82 results in at least one elongate member 75 being formed between adjacent slots 82, elongate member 75 extending between the first and second ends, 72, 73 of tubular member 71, as seen in FIG. 1A.

Still with reference to FIG. 1A, each slot will have first and second ends with a connecting member 77 disposed at the first and second ends of slots 82. Preferably, the first and second ends of each slot 82 are disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Thus, connecting members 77, which are disposed at the first and second ends of each slot 82, and between elongate members 75, will in turn be disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the

tubular member 71. Accordingly, slots 82 are preferably uniformly and circumferentially spaced from adjacent slots, and slots 82 adjacent to one another along the longitudinal axis of tubular member 71 are in a staggered relationship with one another. Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired.

The foregoing described construction of graft, or prothesis, 70 permits graft, or prothesis, 70 to be expanded uniformly, and outwardly, into the configuration shown in FIG. 1B, upon the application of a suitable force from the interior of tubular member 71, as will be hereinafter described in greater detail. The expansion of tubular member 71 into the configuration shown in FIG. 1B is further uniform along the length of tubular member 71, not only because of the uniform spacing between slots 82, as previously described, but also because the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness. As illustrated in FIG. 2, the uniform thickness of elongate member 75 is shown, and the preferred cross-sectional configuration of elongate member 75, connecting member 77, and members 78, 79, is illustrated, which configuration is rectangular. It

should of course be understood by those skilled in the art, that the cross-sectional configuration of the foregoing components of graft, or prothesis, 70 could also be square. As will be hereinafter described in greater detail, it is preferable that the outer surface 74 of graft, or prothesis, 70, which would be in contact with the body passageway 80 FIG. 4), should be relatively smooth.

With reference to FIG. 1B, it is seen that after the graft, or prothesis 70, has been expanded and deformed into the configuration of FIG. 1B, the slots 82 will assume a substantially hexagonal configuration when the tubular member 71 has the second, expanded diameter, d', as shown in FIG. 1B. Such a hexagonal configuration will result when the slots 82 initially have a substantially rectangular configuration when the tubular member 71 has the first diameter, d, illustrated in FIG. 1A. It should be noted that were the width of slots 82 to be substantially reduced, whereby the length of connecting member 77 would approximate a single point intersection, the expansion of such a tubular member 71 would result in slots 82 assuming a configuration which would be substantially a parallelogram (not shown).

It should be noted that not only is tubular member 71 expanded from the configuration shown in FIG. 1A to achieve the configuration shown in FIG. 1B, but tubular member 71 is further "deformed" to achieve that configuration. By use of the term "deformed" is meant that the material from which graft, or prothesis, 70 is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member 71. Accordingly, the force is sufficient to permanently bend elongate members 75 whereby segments

of the elongate members 75 pivot about connecting members 77 and move in a circumferential direction as they pivot, whereby the diameter of the tubular member 71 increases from the first diameter, d, to the expanded diameter, d', of FIG. 1B. The force to be applied to expand tubular member 71, which is applied in the manner which will be hereinafter described in greater detail, must thus be sufficient to not only expand tubular member 71, but also to deform elongate member 75, in the manner previously described, whereby the portions of the elongate members 75 which pivot about the ends of connecting members 77 do not "spring back" and assume their configuration shown in FIG. 1A, but rather retain the configuration thereof in FIG. 1B. Once graft, or prothesis, 70 has been expanded and deformed into the configuration shown in FIG. 1B, graft, or prothesis 70, will serve to prevent a body passageway from collapsing as will be hereinafter described in greater detail. It should be noted that when tubular member 71 has the first diameter, d, shown in FIG. 1A, or after tubular member 71 has been expanded and deformed into the second, expanded diameter, d', of FIG. 1B, tubular member 71 does not exert any outward, radial force, in that tubular member 71 is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force.

With reference now to FIGS. 3 and 4, the methods and apparatus of the present invention will be described in greater detail. Once again, it should be understood that the methods and apparatus of the present invention are useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to

intraluminally reinforce other body passageways or ducts, as previously described. Still with reference to FIGS. 3 and 4, an expandable intraluminal vascular graft, or prosthesis, 70, of the type described in connection with FIGS. 1A and 1B, is disposed or mounted upon a catheter 83. Catheter 83 has an expandable, inflatable portion 84 associated therewith. Catheter 83 includes means for mounting and retaining 85 the expandable intraluminal vascular graft, of prosthesis, 70 on the expandable, inflatable portion 84 of catheter 83. Preferably, the mounting and retaining means 85 comprises retainer ring members 86 disposed on the catheter 83 adjacent the expandable inflatable portion 84 of catheter 83; and a retainer ring member 86 is disposed adjacent each end 72, 73 of the expandable intraluminal vascular graft, or prosthesis, 70. Preferably, as seen in FIG. 3, retainer ring members are formed integral with catheter 83, and the retainer ring member 86 adjacent the leading tip 87 of catheter 83 slopes upwardly and away from catheter tip 87 in order to protect and retain graft or prosthesis, 70 as it is inserted into the lumen 81 of body passageway 80, as to be hereinafter described in greater detail. The remaining retainer ring member 86 as shown in FIG. 3, slopes downwardly away from tip 87 of catheter 83, to insure easy removal of catheter 83 from body passageway 80. After expandable intraluminal graft, or prosthesis, 70 has been disposed upon catheter 83, in the manner previously described, the graft, or prosthesis, 70 and catheter 83 are inserted within a body passageway 80 by catheterization of the body passageway 80 in a conventional manner.

In a conventional manner, the catheter 83 and graft, or prosthesis, 70 are delivered to the desired

location within the body passageway 80, whereat it is desired to expand the lumen 81 of body passageway 80 via intraluminal graft 70, or where it is desired to implant prosthesis 70. Fluoroscopy, and/or other conventional techniques may be utilized to insure that the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway. Prosthesis, or graft, 70 is then expanded and deformed by expanding the expandable, inflatable portion 84 of catheter 83, whereby the prosthesis, or graft, 70 is expanded and deformed radially, outwardly into contact with the body passageway 80, as shown in FIG. 4. In this regard, the expandable, inflatable portion of catheter 83 may be a conventional angioplasty balloon 88. After the desired expansion and deformation of prosthesis, or graft, 70 has been accomplished, angioplasty balloon 88 may be collapsed, or deflated, and the catheter 83 may be removed in a conventional manner from body passageway 80. If desired, as seen in FIG. 3, catheter 83, having graft or prosthesis, 70 disposed thereon, may be initially encased in a conventional Teflon™ sheath 89, which is pulled away from prosthesis, or graft, 70, prior to expansion of the prosthesis, or graft, 70.

Still with reference to FIGS. 3 and 4, it should be noted that tubular member 71 of prosthesis, or graft, 70 initially has the first predetermined, collapsed diameter, d, as described in connection with FIG. 1A, in order to permit the insertion of the tubular member, 71 into the body passageway 80 as previously described. When it is desired to implant prosthesis 70 within a body passageway 80 for the purposes previously described, the prosthesis 70 is expanded and deformed to the second diameter, d', and the second, expanded

diameter, d', is variable and determined by the internal diameter of the body passageway 80, as shown in FIG. 4. Accordingly, the expanded and deformed prosthesis 70, upon deflation of angioplasty balloon 88 will not be able to migrate from the desired location within the body passageway 80, nor will the expansion of the prosthesis 70 be likely to cause a rupture of the body passageway 80. Furthermore, insofar as prosthesis, or graft, 70 is not a "spring-like" or "self-expanding member", the prosthesis is not consistently applying an outward, radial force against the interior surface of body passageway 80, in excess of that required to resist radial ~~collapse~~ collapse of the body passageway 80. Thus, erosion of the interior surface, or intima, of the artery or body passageway is prevented.

When it is desired to use expandable intraluminal graft 70 to expand the lumen 81 of a body passageway 80 having an area of stenosis, the expansion of intraluminal vascular graft 70 by angioplasty balloon 88, allows controlled dilation of the stenotic area and, at the same time controlled expansion and deformation of the vascular graft 70, whereby vascular graft 70 prevents the body passageway 80 from collapsing and decreasing the size of the previously expanded lumen 81. Once again, the second, expanded diameter d' of intraluminal vascular graft 70, as shown in FIG. 4, is variable and determined by the desired expanded internal diameter of body passageway 80. Thus, the expandable intraluminal graft 70 will not migrate away from the desired location within the body passageway 80 upon deflation of angioplasty balloon 88, nor will the expansion of intraluminal graft 70 likely cause a rupture of body passageway 80, nor any erosion as previously described. Further, should an intimal flap,

or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80. In the situation of utilizing graft 70 in the manner previously described to expand the lumen of a portion of a critical body passageway, such as the left main coronary artery, it is believed that the intimal flap will be unable to occlude the left main coronary artery of the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon 88 one time in order to expand and deform graft 70, it is believed that a greater amount of endothelium, or inner layer of the intima, or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid, multicentric endothelialization pattern as shown by experimental studies.

With reference now to FIGS. 5 and 6, prostheses, or grafts, 70 of the type previously described in connection with FIGS. 1A and 1B are shown, and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable

biologically inert coating would be porous polyurethane, Teflon™, or other conventional biologically inert plastic materials. The coating 90 should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft, 70. Coating 90 may be further provided with a means for anchoring 91 (FIG. 6) the tubular member 71 to the body passageway 80. Anchoring means 91 may be comprised of a plurality of radially, outwardly extending projections 92 formed on the coating 90. As seen in FIG. 6, the radially outwardly extending projections 92 could comprise a plurality of ridges 93, or other types of radially, outwardly extending projections. Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials or embodiment shown and described, as obviously modifications and equivalents will be apparent to one skilled in the art. For example, the means for expanding the prosthesis or graft could be a plurality of hydraulically actuated rigid members disposed on a catheter, or a plurality of angioplasty balloons could be utilized to expand the prosthesis or graft. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.